KEY INFORMATION FOR Clinician Communication Behavior in Simulated Patient Encounters

We are asking you to choose whether or not to volunteer for a research study comparing two approaches to improving communication behavior in the setting of serious illness. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn what kinds of communication skills work best and are most acceptable to physicians for improving communication with African American patients and family members. Your participation in this research will last about six hours. You will participate in a simulated encounter with a standardized family member of a patient, which will be videotaped and coded by the research team for communication behavior scores. You will be randomized to receive one of two different kinds of communication skills training following the first simulation; communication skills training with or without additional targeted training on racial bias mitigation. After your training session, you will participate in a second simulated encounter. You will asked to complete an on-line questionnaire and cognitive measurement instrument. You will be asked to provide feedback on a communication training session.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will receive feedback on your communication techniques from a board-certified palliative care physician and from the standardized family member. You will participate in a communication training session. These interventions may help you improve your communication with African American patients with serious illness and their family members. You will receive Continuing Medical Education credits for your participation. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This research poses two main risks to subjects: 1) emotional distress and 2) risk to privacy. Some subjects may find being critiqued on their communication behavior and completing a cognitive tool stressful. There is some risk of breach of privacy from storing videotaped encounters. Every effort will be made to store these videotapes securely to avoid a breach of privacy. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.
As a physician, if you decide not to take part in this study, your choice will have no effect on your employment or performance evaluation.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Elizabeth Chuang. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: email: echuang@montefiore.org, phone: (718) 920-6378.
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called Targeting Bias to Reduce Disparities in End of Life Care: Clinician Communication Behavior in Simulated Patient Encounters (BRiDgE-Sim). Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits.

The researcher in charge of this project is called the "Principal Investigator." Her name is Elizabeth Chuang. You can reach Dr. Chuang at:
Office Address: 1300 Morris Park Ave, Block Building Rm 513
Bronx, NY, 10641
Telephone #:(718) 920-6378
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by the National Institute of Minority Health and Health Disparities

Why is this study being done?

The population of adults over 65 is becoming more racially and ethnically diverse. Despite improvements in the quality of end of life care over the past two decades, significant disparities remain. African American patients and their families report poorer quality care, are more likely to receive ineffective and burdensome care, and are less likely to enroll in hospice at end of life. Effective patient-doctor communication is crucial for improving the quality of end of life care. This study aims to determine the feasibility of a novel physician training intervention to improve quality of communication with African American families.

Why am I being asked to participate?

You are being asked to participate in this study because you are a hospital-based internist, intensivist or oncologist who actively provides care for seriously ill hospitalized patients in the New York City area. If you participate, you will be one of about 50 physicians in this study. This is a single-site study. All study activities will occur at Albert Einstein College of Medicine.

What will happen if I participate in the study?

You will participate in a simulated clinical encounter with a standardized family member (actor) of a hypothetical patient. You will read a clinical vignette describing a seriously ill hospitalized

patient. You will then be asked to discuss goals of care with that hypothetical patient's family member in a videotaped encounter. After this encounter you will receive feedback from a board-certified palliative care physician and the standardized family member. You will be randomized to participate in one of two communication skills training sessions; with and without targeted racial bias mitigation training. Afterwards, you will complete another videotaped simulated encounter. You will also complete an on-line survey and cognitive measurement tool. The survey will include questions about your attitudes and beliefs and questions eliciting your feedback on the communication skills training session.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How many people will take part in the research study?

You will be one of about **50** people who will be participating in this study.

Will there be audio and/or video recording?

Your standardized encounters will be video recorded. You will be assigned a study ID, and your name will not be included with the recordings, however, your face will be identifiable. These recordings will be used only for coding of verbal and nonverbal communication behavior by members of the study team. They will NOT be used as a teaching tool for students or others who are not members of the research staff. The recordings will be stored on a password protected hard drive and will be destroyed 5 years after completion of the study.

Information Banking (Future Use and Storage)

Five years after the study is complete, we will destroy the video recordings, but we will store communication behavior codes and survey responses. We will store this information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies.
Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

If you are an attending physician, you will receive a total of 5.0 AMA PRA Category 1 Continuing Medical Education credits for participating in the simulated encounter with feedback and

communication skills training session. If you choose to withdraw from the study before the session is completed, you will receive credit only for hours completed.

If you are a trainee (resident or fellow), you will receive a total of $50 for your study visit.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

You will be assigned a study ID, and your name will not be included with your survey responses, responses to the cognitive tool or coded communication behavior data.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate

to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

We do not think there are any physical risks related to participating in this research study.

Some subjects may find being critiqued on their communication behavior stressful.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Questionnaire
You may feel uncomfortable answering questions about your attitudes and beliefs or completing the cognitive tool. You can choose not to answer questions that make you feel uncomfortable.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include learning new skills to improve communication with seriously ill patients and their families.

What choices do I have other than participating in this study?

You can refuse to participate in the study. You can obtain training in communication skills from other commercial and non-commercial programs.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date